

# Determinants of health-related quality of life in morbid obese candidates to gastric banding

L. Busetto<sup>1</sup>, V. Pilone<sup>2</sup>, A.M. Schettino<sup>3</sup>, N. Furbetta<sup>4</sup>, M. Zappa<sup>5</sup>, A. Di Maro<sup>6</sup>, V. Borrelli<sup>7</sup>, C. Giardiello<sup>8</sup>, M. Battistoni<sup>9</sup>, A. Gardinazzi<sup>10</sup>, N. Perrotta<sup>11</sup>, G. Micheletto<sup>12</sup>, P. De Meis<sup>13</sup>, S. Martelli<sup>14</sup>, M. Marangon<sup>1</sup>, P. Forestieri<sup>2</sup>, C. Pari<sup>3</sup>, S. Gennai<sup>4</sup>, and E. Mozzi<sup>5</sup>, for the Italian Group for Lap-Band\*

<sup>1</sup>Clinica Medica I, Policlinico Universitario, Padova, <sup>2</sup>Dip. Chirurgia Generale, Oncologica, Bariatrica e Videoassistita, Università degli Studi Federico II, Napoli, <sup>3</sup>U.O. di Chirurgia, Casa di Cura Malatesta Novello, Cesena, <sup>4</sup>U.O. Chirurgia, Casa di Cura Leonardo, Empoli, <sup>5</sup>Cattedra di Chirurgia Generale, Università degli Studi di Milano - Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano, <sup>6</sup>Istituto Ninetta Rosano, Clinica Tricarico, Belvedere Marittimo, <sup>7</sup>Presidio Ospedaliero S. Scolastica, Cassino, <sup>8</sup>U.O.C. Chirurgia Generale, d'Urgenza e Metabolica, Centro per il trattamento dell'Obesità, Presidio Ospedaliero Pineta Grande, Castelvolturno, <sup>9</sup>II Chirurgia Generale, Servizio di Chirurgia dell'Obesità, A.O. Università Integrata, Verona, <sup>10</sup>Ospedale Generale S. Orsola, Fondazione Poliambulanza, Brescia, <sup>11</sup>U.O.C. Chirurgia Generale, Ospedale di Villa d'Agri, A.S. Potenza, <sup>12</sup>Cattedra di Chirurgia Generale, Università degli Studi di Milano - U.O.C. di Chirurgia Generale, Istituto Clinico Sant'Ambrogio, Milano, <sup>13</sup>Presidio Ospedaliero dell'Annunziata, Sulmona, <sup>14</sup>Villa Maria Pia Hospital, Torino, Italy

**ABSTRACT. OBJECTIVE:** To analyse determinants of self reported health-related quality of life (HR-QoL) in morbid obese patients candidates to laparoscopic adjustable gastric banding (LAGB). **METHODS:** Determinants of HR-QoL were investigated in 383 morbid obese patients (82 M and 301 F) with BMI $\geq$ 40 kg/m<sup>2</sup> (BMI $\geq$ 35 kg/m<sup>2</sup> if complicated obesity) and age 18-60 years. HR-QoL was determined with the SF-36 questionnaire. Determinants of the two summary measures of SF-36 (physical component and mental component) were analysed by stepwise multiple linear regression analysis with age, BMI, physical comorbidities, mental comorbidities and eating behaviour disorders as independent variables. Physical comorbidities (diabetes, hypertension, hypertriglyceridemia, low HDL, sleep apnea and osteoarthritis) were coded as present or absent on the basis of simple diagnostic clinical criteria; mental comorbidities (depression) and eating behaviour disorders (binge eating, sweet eating and nibbling) on the basis of an unstructured clinical interview. **RESULTS:** Mean age was 38.8 $\pm$ 10.2 years and mean BMI was 41.5 $\pm$ 5.4 kg/m<sup>2</sup>. Scores in the eight SF-36 subscales were lower in women than in men and lower than in the general Italian population. However, 18.4-43.5% of the participants had HR-QoL levels above the normative values, depending on the scale. In both genders, low scores in the mental component of the SF-36 were associated to the presence of depression and eating behaviour disorders and not to physical comorbidities or BMI levels. Low physical self-perceived well being was associated to high BMI levels in men and to depression, hypertension and hypertriglyceridemia in women. **CONCLUSION:** HR-QoL was poor in morbid obese candidates to LAGB, particularly in women, and was negatively affected more by mental comorbidities and eating behaviour disorders than by physical comorbidities or BMI levels.

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\*Members and affiliations/institutions of the Italian Group for Lap-Band (Gruppo Italiano Lap-Band - GILBPLUS) are listed in the Appendix

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## Correspondence to:

Dr. Luca Busetto, Clinica Medica I, Policlinico Universitario, via Giustiniani 2, 35128 Padova, Italy  
E-mail: luca.busetto@unipd.it

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## INTRODUCTION

Health related quality of life (HR-QoL) refers to the overall effects of medical conditions on physical, mental, and social functioning and well-being as subjectively evaluated and reported by the patient (1). A poor self-reported HR-QoL has been observed in obese patients (2). The impairment in HR-QoL was found to be directly

dependent from the level of obesity, being particularly important in morbid obese patients as compared to overweight or less severely obese subjects (3). HR-QoL in obese people was also affected by the clinical setting to which the patients belonged, being more severe in obese patients seeking treatment than in non-treatment seeking subjects (4). The category of obese patients with the most significantly impaired levels

of HR-QoL was represented by morbid obese patients seeking bariatric surgical therapy (4). In these patients, weight loss induced by surgery may hopefully contribute significantly not only to the effective treatment of obesity and related comorbidities, but also to the improvement of the poor self-perception that morbid obese patients have of their own health and lives.

Previous studies investigating HR-QoL in morbid obese candidates to bariatric surgery uniformly confirmed that these patients had HR-QoL levels significantly lower than the corresponding national norms (5-10), but also evidenced a substantial degree of internal variability, with some morbid obese patients having extremely reduced HR-QoL and some patients not showing a significant reduction in self-perceived well being (7-10). The reasons of this variability have not been extensively explored so far. Both the presence of somatic complaints and comorbidities (10-12) and the presence of mental disorders (12, 13) were found separately to be associated to lower HR-QoL levels in obese subjects. Moreover, the possible relative role of any factor in determining HR-QoL in obese patients may be influenced by the type of instrument used to measure HR-QoL, with disease specific instruments, such as the Impact of Weight on Quality of Life (IWQOL) questionnaire or others, more sensitive to the effects of weight and weight-related problems on self-perceived well being (4, 14), and generic instruments, such as the SF-36 questionnaire, more prone to identify the effect of aspects of the disease that are not strictly related to body weight, such as eating behavior disorders and related psychopathology (12).

A more precise identification of the distinct role of mental and physical disorders as determinants of individual HR-QoL levels in morbid obese patients candidates to bariatric surgery may be clinically relevant. Indeed, we may suppose that HR-QoL may improve consensually with weight loss, if its baseline level was determined mainly by obesity-related physical factors. On the contrary, the improvement of HR-QoL after surgery may be less relevant or only transient, if the poor pre-operative HR-QoL was the consequence of mental factors not improved or non completely corrected by weight loss.

The objective of our study was therefore to investigate the relative role of physical and mental factors as possible determinants of HR-QoL levels in a group of morbid obese patients candidates to bariatric surgery. For this purpose, the baseline pre-operative data collected in participants enrolled in a prospective three-year multi-

center Italian study on the changes of HR-QoL in patients treated with laparoscopic adjustable gastric banding (LAGB) were used. In this study, HR-QoL was analyzed by the use of the 36-item Health Survey (SF-36) questionnaire form.

## METHODS

### *Patients and procedures*

The Italian Group for Lap-Band (*Gruppo Italiano Lap-Band - GILBPLUS*) has a centralized electronic database collecting operative and follow-up data from Italian surgical centres that utilize the Lap-Band® System (Allergan Medical, Irvine, CA) as LAGB procedure. Participation of the centres to the database is on a voluntary basis. In 2008, GILBPLUS designed an ongoing prospective three-year observational study on the changes of HR-QoL in patients treated with LAGB. Inclusion and exclusion criteria were in accordance to the standard international guidelines for bariatric surgery (Table 1) (15, 16). From June 2008 to December 2009, 383 morbid obese candidates to LAGB (82 men and 301 women) were enrolled in 13 Italian bariatric surgery centres participating in the GILBPLUS study (see *Appendix*) and underwent LAGB surgery by using the LAP-BAND AP® Adjustable Gastric Banding System (Allergan Medical, Irvine, CA). Mean age was  $38.8 \pm 10.2$  years (range 19-60 years) and mean BMI was  $41.5 \pm 5.4$  kg/m<sup>2</sup> (range 35.0-77.0 kg/m<sup>2</sup>). Each patient gave written informed consent for the study participation. Only baseline pre-operative data were used in the present report.

A pre-operative multidisciplinary assessment

**TABLE 1**  
Inclusion and exclusion criteria for the GILBPLUS prospective three-year observational study on the changes of HR-QoL in patients treated with laparoscopic adjustable gastric banding (LAGB).

Inclusion criteria	<ol style="list-style-type: none"> <li>1. BMI <math>\geq 40</math> kg/m<sup>2</sup> or BMI <math>\geq 35</math> kg/m<sup>2</sup> in patients with comorbidities expected to improve with weight loss.</li> <li>2. Age 18-60 years.</li> <li>3. Previous failure to lose or maintain weight loss with medical management.</li> </ol>
Exclusion criteria	<ol style="list-style-type: none"> <li>1. Patient unable to participate in prolonged medical follow-up</li> <li>2. Non-stabilized psychotic disorders, severe depression and personality disorders.</li> <li>3. Alcohol abuse and/or drug dependencies</li> <li>4. Diseases threatening life in the short term</li> <li>5. Patients who are unable to care for themselves and have no long-term family or social support that will warrant such care.</li> </ol>

of the patients was performed in all centres. Basic multidisciplinary assessment included patients clinical history, physical examination, psychological evaluation, blood tests, electrocardiography, chest radiology, spirometry, abdominal ultrasonography and esofagogastroduodenoscopy. Additional tests and consultations were scheduled if clinically appropriate. All clinical data were electronically stored in a centralized electronic database.

### Measures

Specific questions about preoperative comorbidities were included in the GILBPLUS database. At baseline, diabetes was defined as a fasting plasma glucose level  $\geq 126$  mg/dl or use of any anti-diabetic drug (17). Hypertriglyceridemia was defined as fasting triglycerides  $\geq 150$  mg/dl and low HDL as HDL-cholesterol levels  $< 40$  mg/dl in men and  $< 30$  mg/dl in women (18). Hypertension was defined as blood pressure  $\geq 140/90$  mmHg or use of any anti-hypertensive drug (19). Sleep apnea was diagnosed on the basis of the presence of subjective diurnal and/or nocturnal symptoms (20). An instrumental registration of the breathing pattern during sleep was not mandatory. Osteoarthritis was clinically defined as the presence of chronic pain at the weight-bearing joints with or without the use of pain-suppressant medications.

As part of the pre-operative multidisciplinary assessment, eating behavior disorders, eating attitudes and psychological symptoms were evaluated in all patients during a clinical unstructured interview performed by an experienced psychologist. Psychiatric consultation was not routinely performed, but it was requested in case of suspected severe psychiatric comorbidity. Patients with psychotic disorders, severe depression and personality disorders were excluded (16) (Table 1). Patients with mild-to-moderate major depressive disorder or dysthymic disorder, defined according to the diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) (21), were included and simply categorised as affected by depression. The diagnosis of binge eating disorder (BED) was also based on the proposed DSM-IV diagnostic criteria (21). No formal testing was requested for the diagnosis of BED and no attempts were made to categorize the patients according to the severity of the disorder. Sweet Eating was diagnosed when the patient craves simple carbohydrates, and carbohydrate craving could be continuously present or triggered by emotional (anxiety, stress) or physiological (premenstrual phase) situations (22). Nibbling was diagnosed

when the patient eats small quantities of foods repetitively between meals, typically triggered by inactivity and/or loneliness (22).

HR-QoL was analyzed by the use of the 36-item Health Survey (SF-36) questionnaire form. The SF-36 measures the following eight subscales: physical functioning (PF), social functioning (SF), role limitations due to a physical problem (RP), role limitations due to an emotional problem (RE), mental health (MH), vitality (VT), bodily pain (BP), and general health (GH) perception. The eight subscales form two distinct higher-ordered summary scales: the physical component summary scale (PCS), mainly based on physical functioning, role limitations due to a physical problem, pain, and general health perception; and the mental component summary scale (MCS), mainly reflecting social functioning, role limitations due to an emotional problem, mental health, and vitality (23). SF-36 has an Italian validated version and normative values have been published for the Italian adult population (24).

### Statistical analysis

All statistical analyses were performed using SPSS statistical package, version 16.0 (SPSS, Chicago, IL). In all analyses, a  $p$ -value  $< 0.05$  was considered to be statistically significant. Frequencies, mean values and standard deviations were used to describe the baseline characteristics of the patients. Differences between genders were evaluated by unpaired Student's  $t$ -test for numerical variables and Chi-square test for categorical variables.

Giving the significant differences observed between genders in HR-QoL levels, determinants of the two summary measures of SF-36 (PCS and MCS) were analysed separately in men and women. A multiple linear regression analysis model was used. Age, BMI, physical comorbidities (type 2 diabetes, hypertriglyceridemia, low HDL, hypertension, sleep apnea, osteoarthritis), depression and eating behaviour disorders (binge eating disorder, sweet eating, nibbling) were entered as independent variables. Categorical covariates was coded as absent (=0) or present (=1). Predictors were selected by use of a stepwise procedure with a significance level of  $< 0.05$ . As a criterion for removing variables in the stepwise regression, a  $p$ -value for  $F$  of  $\geq 0.10$  was chosen.

## RESULTS

### Baseline HR-QoL levels

The baseline characteristics of the 383 morbid obese participants in the GILBPLUS

**TABLE 2**

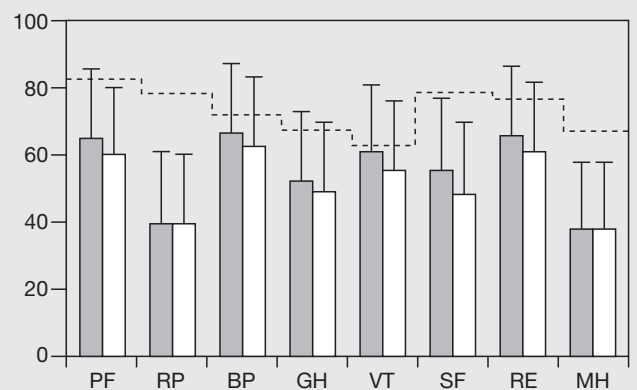
Baseline characteristics in morbid obese patients enrolled in the GILBPLUS prospective three-year observational study on the changes of HR-QoL in patients treated with LAGB.

	Men (N=82)	Women (N=301)	p-value
Age, years	39.2±9.6	38.7±10.4	0.694
Body weight, kg	128.7±17.5	108.9±15.7	0.000
BMI, kg/m <sup>2</sup>	41.9±5.0	41.4±5.5	0.483
Type 2 diabetes (%)	12.2%	10.0%	0.342
Hypertriglyceridemia (%)	18.3%	8.6%	0.014
Low HDL levels (%)	11.0%	6.0%	0.097
Hypertension (%)	41.5%	21.3%	0.000
Sleep Apnea (%)	19.5%	5.3%	0.000
Osteoarthritis (%)	15.9%	22.3%	0.132
Binge Eating (%)	6.1%	3.7%	0.242
Sweet Eating (%)	0.0%	5.5%	0.025
Nibbling (%)	11.0%	12.6%	0.426
Depressive symptoms (%)	6.1%	11.3%	0.117

Mean values ± Standard Deviation were reported for numerical variables.

prospective three-year observational study on the changes of HR-QoL in patients treated with LAGB are reported in Table 2. No gender differences in age (39.2±9.6 years in men; 38.7±10.4 years in women) or BMI levels (41.9±5.0 kg/m<sup>2</sup> in men; 41.1±5.5 kg/m<sup>2</sup> in women) were observed. Male patients were more frequently affected by hypertension (41.5% vs 21.3%;  $p<0.001$ ), hypertriglyceridemia (18.3% vs 8.6%;  $p<0.05$ ), and sleep apnea symptoms (19.5% vs 5.3%;  $p<0.001$ ) than female patients.

The HR-QoL levels in men and women are shown in Figure 1. Scores in the eight SF-36 subscales were generally lower in women than in men and lower than in the general adult Italian population. Men had statistically higher scores than women both at the PCS (55.5±12.0 vs 51.8±11.3;  $p<0.05$ ) and at the MCS (54.2±12.0 vs 50.4±12.5;  $p<0.05$ ). The distribution of PCS and MCS in the sample is shown in Figure 2. The distribution was normal in both scales, but a substantial variability may be observed: both patients with extremely poor and patients with very well preserved HR-QoL levels were included. The same pattern of distribution may be observed in the eight SF-36 subscales (data not shown). Despite the majority of the patients had scores in the eight subscales lower than the normative values of the Italian adult population, a proportion of patients still have HR-

**FIGURE 1**

Health-related quality of life (HR-QoL) levels in 82 morbid obese men (gray bars) and 301 morbid obese women (white bars) enrolled in the GILBPLUS prospective three-year observational study. The eight subscales of the SF-36 questionnaire form are indicated: physical functioning (PF), role limitations due to a physical problem (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to an emotional problem (RE) and mental health (MH). The dotted line represents normative values in the Italian adult population (19). Differences between genders were tested by unpaired Student's t-test. Men had significantly higher HR-QoL levels than women in PF ( $p<0.05$ ), VT ( $p<0.05$ ) and SF ( $p<0.05$ ).

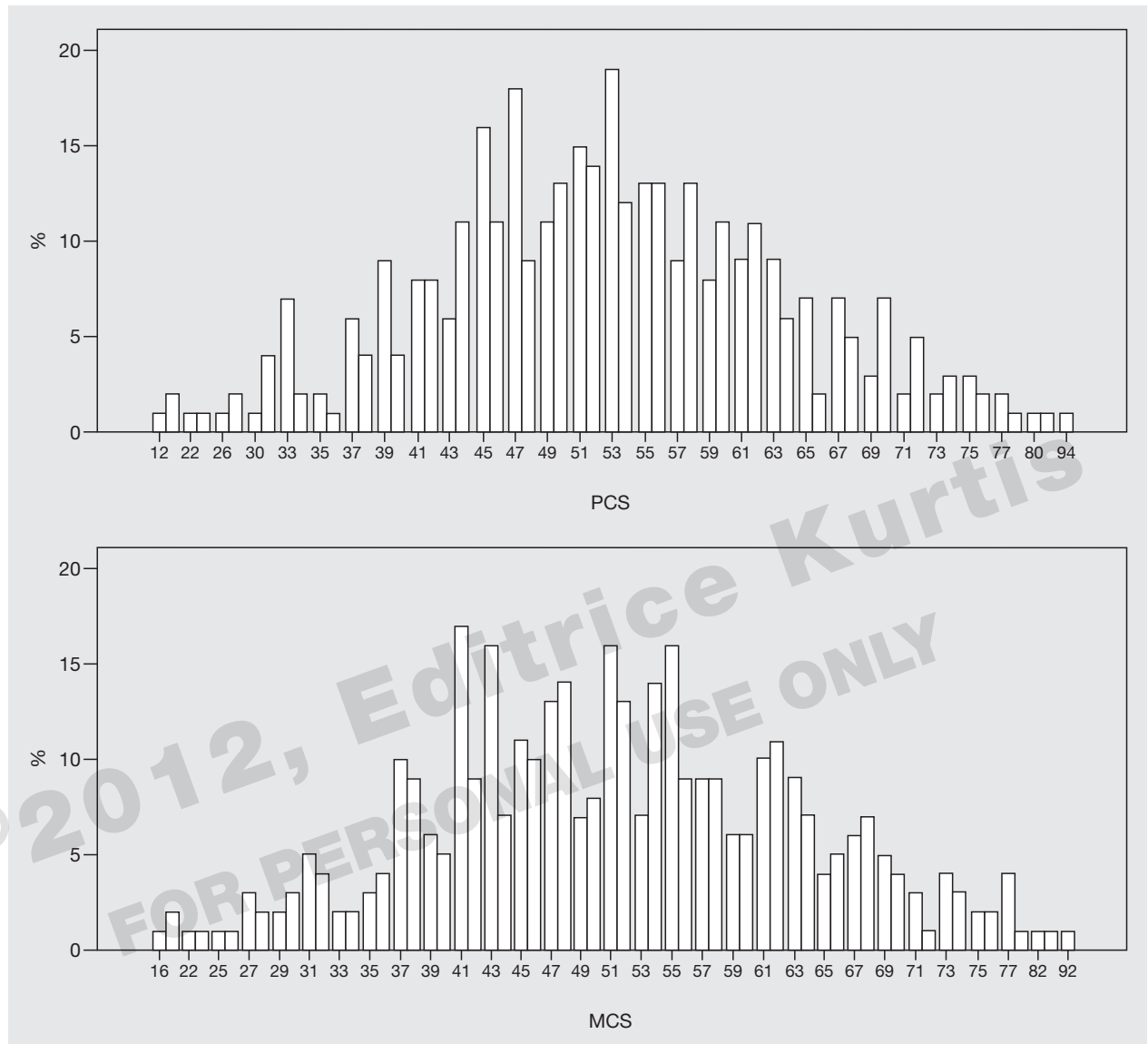
QoL above the normative values. In particular, the proportion of patients with HR-QoL levels above the normative values was 18.4% in the PF subscale, 18.4% in RP, 41.3% in BP, 29.3% in GH, 11.7% in SF, 23.5% in RE, 43.5% in VT, and 20.0% in MH.

#### Determinants of HR-QoL

Determinants of PCS and MCS variability were investigated separately in men and women by a stepwise multiple linear regression analysis (Table 3). In both genders, low scores in the mental component of the SF-36 (MCS) were associated to the presence of depression and eating behaviour disorders (binge eating in men and sweet eating in women) and not to physical comorbidities or BMI levels. Low physical self-perceived well being (PCS) was associated to high BMI levels in men and to depression, hypertension and hypertriglyceridemia in women. However, our model explained only a small fraction of the PCS and MCS variability. Explained variance was 7% for PCS variability in both genders, 14% for MCS in men, and 6% for MCS variability in women.

## DISCUSSION

In this study, we analyzed the levels and determinants of self reported HR-QoL in a



**FIGURE 2**

Distribution of the Physical Component Summary scale (PCS) and the Mental Component Summary scale (MCS) scores of the SF-36 in 383 morbid obese patients enrolled in the GILBPLUS prospective three-year observational study.

large group of morbid obese patients seeking bariatric surgery and enrolled in a multicentre prospective study on the changes of HR-QoL in patients treated with LAGB. We confirmed that in morbid obese candidates to bariatric surgery, particularly in women, HR-QoL was poor and lower than in the general population. However, we also demonstrated a substantial variability in HR-QoL before surgery, with most of the patients having a poor self reported HR-QoL, but some patients reporting a very preserved self-perceived well being. In both sexes, HR-QoL was negatively affected, particularly in its mental component, more by the

presence of depression and eating behaviour disorders than by physical comorbidities or BMI levels.

Several population studies reported a negative correlation between BMI levels and HR-QoL in the general population (2, 25). The association between obesity and low HR-QoL levels was maintained even after controlling for the possible confounding effect of the presence of chronic diseases (26) and obesity-related comorbidities (27). However, the impairment of HR-QoL observed in obesity may be influenced by patients setting. In a large meta-analysis including 54 articles and a total number of

**TABLE 3**

Determinants of HR-QoL in 82 morbid obese men and 301 morbid obese women enrolled in the GILBPLUS prospective three-year observational study.

	Explained variance	Significant predictors
<b>Men</b>		
PCS	R <sup>2</sup> : 0.068	BMI ( $\beta$ -coeff: -0.6; SE: 0.3; $p=0.021$ )
MCS	R <sup>2</sup> : 0.146	Binge eating ( $\beta$ -coeff: -17.9; SE: 5.8; $p=0.003$ ) Depression ( $\beta$ -coeff: -11.7; SE: 5.8; $p=0.047$ )
<b>Women</b>		
PCS	R <sup>2</sup> : 0.071	Depression ( $\beta$ -coeff: -6.5; SE: 2.1; $p=0.002$ ) Hypertension ( $\beta$ -coeff: -3.4; SE: 1.6; $p=0.033$ ) Hypertriglyceridemia ( $\beta$ -coeff: -4.6; SE: 2.3; $p=0.042$ )
MCS	R <sup>2</sup> : 0.061	Depression ( $\beta$ -coeff: -8.2; SE: 2.3; $p=0.000$ ) Sweet eating ( $\beta$ -coeff: -6.7; SE: 3.2; $p=0.038$ )

PCS: Physical Component Summary Scale; MCS: Mental Component Summary Scale. Results of a stepwise multiple linear regression analysis model are presented. Scores at the two summary measures (PCS and MCS) of the SF-36 were entered as dependent variable. Age, BMI, physical comorbidities (type 2 diabetes, hypertriglyceridemia, low HDL, hypertension, sleep apnea, osteoarthritis), depression, and eating behaviour disorders (binge eating, sweet eating, nibbling) were entered as independent variables. Predictors were selected at a significance level of  $<0.05$ . As criterion for removing variables in the stepwise regression, a  $p$ -value for  $F$  of  $\geq 0.10$  was chosen.  $\beta$ -coefficient ( $\beta$ -coeff), standard error (SE), and  $p$ -value ( $p$ ) are indicated.

nearly 100,000 participants, van Nounen et al. clearly demonstrated that HR-QoL was more impaired in patients seeking bariatric surgical treatment than in patients seeking conservative treatment or in non-treatment-seeking subjects, even after adjusting for BMI levels (4). Several studies confirmed that bariatric surgery candidates have HR-QoL levels lower than specific national normative values (5-10, 13). In agreement with these studies, we confirmed a severe impairment of HR-QoL in a large group of morbid obese candidates to LAGB enrolled in Italian bariatric centres well disseminated in our national territory. Some previous observation reported that obese patients were more dysfunctional in physical than in emotional subscales of the SF-36 (11, 13). In our sample, reduction of HR-QoL was observed both in physical and in emotional domains.

The presence of a substantial variability in HR-QoL levels also within the morbid obese patients seeking bariatric surgery group was evident in several reports (6-9, 13), but it has not previously emphasized or quantified. In our sample, the majority of patients had scores in the eight SF-36 subscales lower than Italian normative values, but 18 to 43% of them, depending on the scale, showed HR-QoL levels

above the normative values. A more precise knowledge of the determinants of this variability may be clinically useful in the management of morbid obesity. In our study, the two summary measures (Physical Component and Mental Component) of the SF-36 questionnaire were negatively affected more by the presence of mental comorbidities and eating behaviour disorders than by physical comorbidities or BMI levels. In particular, the presence of depression was found to be associated with a reduction of both physical and mental HR-QoL domains in women and with a reduction of mental HR-QoL domain in men.

Previous studies investigating the determinants of HR-QoL in obesity concentrated on the possible role of physical comorbidities. In an English population study, the decline of HR-QoL observed in people with high BMI levels was further emphasised by the presence and the number of chronic illnesses (11). In a cohort of 163 Australian morbid obese patients candidates to LAGB, HR-QoL levels were lower in subjects with clinical knee osteoarthritis than in subjects without knee problems (10). Finally, in a mixed cohort of obese and normal-weight subjects, higher numbers of current somatic disorders negatively predicted the physical dimension of HR-QoL (12). In our study, the role of comorbidities as HR-QoL determinants was very small and limited to the physical dimension. However, the diagnosis of comorbidities before surgery in the GILBPLUS database was based on very simple clinical criteria. Therefore, the effect of current comorbidities on HR-QoL could have been attenuated by some degree of missing diagnosis or by the fact that comorbidities have been simply classified as present or absent, irrespective of their clinical severity.

Other determinants of HR-QoL in obesity have been searched in the socio-economic domain. In a cross-sectional survey of rural Spanish women, the impact of obesity on women's HR-QoL was greater among those with a lower educational level (28). Among overweight or obese men reporting strong social support, physical HR-QoL was not impaired as in men with less social support (29). Unfortunately, no variables related to the socio-economic or educational levels were included in the GILBPLUS database.

Surprisingly, very few studies evaluated the role of mental disturbances and eating behaviour disorders with respect to self-perceived well being in obese subjects. In a mixed cohort of obese and normal-weight subjects, higher numbers of current mental disorders negatively predicted both the physical and the mental

dimension of HR-QoL (12). In a previous report of the same group, binge eating disorder, depression and low self-esteem had a profound negative impact on HR-QoL in morbidly obese pre-surgery patients (13). In our study, the presence of depression was found to be associated to a reduction of both mental and physical self-perceived well being in women and to a reduction of the mental component of HR-QoL in men. Binge eating and sweet eating also seem to play a role, showing negative associations with the mental component in men and women respectively.

The most relevant limitation of our multicenter study is the poor quality of diagnostic methodology used for the determination of both somatic and mental comorbidities before surgery. As previously discussed, physical comorbidities were diagnosed with very simple clinical criteria and not categorized according to their severity. Moreover, the presence of depression and eating behaviour disorders was tested with the use of an unstructured clinical evaluation and without the application of any formal testing. The use, in our study, of an unstructured method for the determination of mental comorbidities may have produced a certain degree of misdiagnosis and precluded an analysis according to the disorders' severity. Studies examining the agreement of psychiatric diagnoses obtained during routine clinical evaluation prior to bariatric surgery and diagnoses obtained separately in a research clinic using formal testing raised questions concerning the diagnostic reliability of simple clinical methods (30). These limitations in diagnostic accuracy should be taken into account in evaluating the results of our study, but they should be partly compensated by the rather high number of participants and the multi-center design.

In conclusion, our results confirmed that HR-QoL was severely impaired in morbid obese patients seeking bariatric surgery. However, a substantial variability in HR-QoL levels was observed also within this very particular group of patients. Our analysis demonstrated that the presence of mental comorbidities and/or eating behaviour disorders was associated to a reduction of self-perceived well being. The presence and relevance of this association need to be taken into account in the evaluation of morbid obese patients before surgery and in the analysis of the changes of HR-QoL after the procedure. The persistence or recurrence of depression and/or eating disorders in the follow-up may indeed attenuate the positive effects of bariatric surgery on HR-QoL or induce a late novel deterioration of HR-QoL in the phase of weight stabilisation, when the positive psycho-

logical effects of rapid and successful weight loss tend to vanish. This hypothesis will be specifically investigated in the prospective post-operative phase of the ongoing GILBPLUS three-year observational study on the changes of HR-QoL in patients treated with LAGB.

## APPENDIX

The following investigators and institutions participated in the Italian Group of Lap-Band (*Gruppo Italiano Lap-band – GILBPLUS*) prospective three-year observational study on the changes of HR-QoL in patients treated with LAGB. The number of cases enrolled at each centre is in parentheses:

A.M. Schettino, C. Pari, V. Pasini, U.O. di Chirurgia, Casa di Cura Malatesta Novello, Cesena (52); V. Pilone, P. Forestieri, S. Tramontano, Dipartimento di Chirurgia Generale, Oncologica, Bariatrica e Videoassistita, Università degli Studi Federico II, Napoli (45); F. Furbetta, S. Gennai, N. Furbetta, U.O. di Chirurgia, Casa di Cura Leonardo, Empoli (43); E. Mozzi, E. Lattuada, M. Zappa, Cattedra di Chirurgia Generale, Università degli Studi di Milano - Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano (41); A. Di Maro, S. Civitelli, Istituto Ninetta Rosano, Clinica Tricarico, Belvedere Marittimo (32); V. Borrelli, M. Giuffrè, Presidio Ospedaliero S. Scolastica, Cassino (31); C. Giardiello, V. Antognozzi, U.O.C. Chirurgia Generale, d'Urgenza e Metabolica, Centro per il trattamento dell'Obesità, Presidio Ospedaliero Pineta Grande, Castel Volturno (30); M. Battistoni, M. Genna, II Chirurgia Generale, Servizio di Chirurgia dell'Obesità, Azienda Ospedaliera Universitaria Integrata, Verona (26); A. Gardinazzi, M. Bazzana, Ospedale Generale Classificato di Zona S. Orsola, Fondazione Poliambulanza, Brescia (24); N. Perrotta, A. Cappiello, U.O.C. di Chirurgia Generale, Ospedale di Villa d'Agri, Azienda Sanitaria di Potenza (22); G. Micheletto, E. Moroni, Cattedra di Chirurgia Generale, Università degli Studi di Milano - U.O.C. di Chirurgia Generale, Istituto Clinico Sant'Ambrogio, Milano (20); P. De Meis, Presidio Ospedaliero dell'Annunziata, Sulmona (11); S. Martelli, Villa Maria Pia Hospital, Torino (6).

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